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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,553	09/30/2003	Erik J. van der Burg	MVMDINC.ICP1C3	5764

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EXAMINER
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DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,553

Applicant(s)

VAN DER BURG ET AL.

Examiner

Glenn K. Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36, 38-64 and 66-119 is/are pending in the application.
- 4a) Of the above claim(s) 13, 19-21, 25-27, 34-36, 44, 63, 72-76, 104 and 112 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 38-50, 55 and 85-91 is/are allowed.
- 6) ☒ Claim(s) 6-12, 14-18, 22-24, 28-33, 51-54, 56-61, 64, 66-71, 77-84, 92-103, 105-111 and 113-119 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-23-06, 7-8-05, 7-6-01</u> | 6) <input type="checkbox"/> Other: _____  |

### ***Election/Restrictions***

Claims 13,19-21,25-27,34-36,63,72-76,104 and 112 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08-31-2005. Claim 63 was added to the list of withdrawn claims, as it calls for the device to be in the shape of a disc. The embodiment of fig. 6 is not disc-shaped... it could be described as being "cylindrical". The balloon may be part of a device to enlarge the device shown in fig. 6; however, the species elected shown in fig. 6 does not have the balloon. The device of fig. 6 with the balloon to enlarge it would be a subspecies... another one is the device being made out of a self-expanding material. The examiner contends that the embodiment chosen was the latter, however, if the applicant would like to clarify the election to include the balloon-expandable version, then the examiner requests that applicant specify the same. It should also be pointed out that when the device is detached from the delivery device, that the balloon would not be part of the device as the balloon is not believed to be left behind in the LAA. Fig. 6 also fails to show the rotatably coupling of the device to the delivery device.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-12, 14-18, 30-33, 51, 52, 54, 56-61, 64, 92-103, 105-111 and 113-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Whayne, et al.-5865791.

Whayne discloses a method of closing and occluding an LAA using an expandable mesh device 95. As disclosed in col. 11 lines 5-26 and col. 12 lines 10-60, the mesh can either be placed over the inverted LAA or placed in the LAA or can be placed over the sack entrance to prevent thrombus from moving from the pouch into the atrium. The device is placed by a delivery catheter through a guiding catheter. The mesh can be used in conjunction with an anchoring member. See col. Col. 10 lines 45-67 and fig. 27.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-24,28,29,53,66-71 and 77-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne, et al.-'791.

Whayne discloses the invention as claimed with the exception of the device conforming to the inside wall of the LAA. However, as the mesh self-expands, and since it blocks thrombus from leaving the LAA and since it acts as a support for the LAA, it would have been obvious to have used a mesh of a large enough size to occupy the LAA (and thus contact and conform to the inner wall of the LAA) so that the pouch would not unnecessarily move during heart contractions or blood flow. To have delivered the mesh by catheter trans-septally would have been an obvious method step to perform as access to the heart as commonly achieved in this manner.

***Allowable Subject Matter***

Claims 1-5,38-50,55 and 85-91 are allowed.

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 02-23-2006 have been fully considered but they are not persuasive.

Even when using the sutures, it is the mesh which would prevent the thrombus from leaving or entering the reduced diameter LAA.

The outer perimeter of the mesh is the frame and the links are the pieces of the mesh which extend between nodes or places of intersection of the wire elements of the mesh. The mesh forms a barrier and blocks the opening to the LAA.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
15 May 2006

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